James C. Pistorino (SBN 226496)
james@dparrishlaw.com
Parrish Law Offices
224 Lexington Dr.
Menlo Park, CA 94025
Telephone: (650) 400-0043

Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MRS. SHARON ZIEROTH,

Plaintiff

v.

ALEX AZAR, in his capacity as Secretary of the United States Department of Health and Human Services,

Defendant

Case No. _____

COMPLAINT
ADMINISTRATIVE PROCEDURE ACT CASE

JURY TRIAL DEMANDED

1. Plaintiff Mrs. Sharon Zieroth brings this action against Defendant Alex Azar, in his official capacity as Secretary of the United States Department of Health and Human Services, to obtain injunctive relief for violation of federal law. Plaintiff makes the following allegations based on the investigation of counsel and on information and on personal knowledge.

I. JURISDICTION

2. This Court has jurisdiction over this action pursuant to 42 U.S.C. § 405(g) and 1395ff. Mrs. Zieroth is filing suit after a final decision of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of her Medicare claim (and, therefore, has exhausted her administrative remedies), the amount-in-controversy is more than $1,650 (42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days (plus extensions) of the Secretary's final decision.

3. Venue is proper in this district pursuant to 42 U.S.C. § 1395ff(b)(2)(C)(iii) because this action is being brought in the Northern District of California.

II. PARTIES

4. Plaintiff Sharon Zieroth is an individual and a resident of the State of California. Mrs. Zieroth is eligible for Medicare on the basis of age or disability as previously determined by the Secretary.

5. Defendant Alex Azar is sued in his official capacity as the Secretary of Health and Human Services.

III. INTRADISTRICT ASSIGNMENT

6. Mrs. Zieroth is a resident of Contra Costa County, California. Pursuant to L.R. 3-5(b) and 3-2(c), it is believed that assignment to either the San Francisco or Oakland divisions would be appropriate.

IV. FACTUAL BACKGROUND

7. Diabetes is a disease in which the body either does not produce any/enough insulin (Type I) or does not properly respond to/regulate blood glucose levels (Type II). As a result, the individual may experience high or low blood glucose levels for a prolonged period of time. High or low blood glucose levels for long periods lead to heart disease, stroke, kidney failure, ulcers (sometimes resulting in amputation), eye damage (sometimes resulting in blindness), and ultimately death. As of 2015, diabetes was the seventh leading cause of death in the United States.[1] Through 2012, the costs related to diabetes (healthcare and lost productivity) were estimated at $245 billion annually.[2]

8. In addition to monitoring through blood tests (see below), many diabetics feel physical symptoms such as blurred vision, fatigue, hunger, and increased thirst that alert them their blood glucose levels are too high or too low. As a result, the diabetic is able to take corrective action (*e.g.*, drinking orange juice).

9. However, the longer patients live with diabetes, the more they lose sensitivity to out of range glucose levels. Thus, they no longer have any physical sense that their glucose level may be too high or too low, and therefore lose this indication that corrective action must be taken. This is referred to as "hyperglycemic or hypoglycemic unawareness" And Mrs. Zieroth suffers from this condition.

10. In addition, most Type I diabetics including Mrs. Zieroth suffer serious medical complications due to their diabetes including blindness, stroke, loss of limb, nerve damage, and brain damages, and possible death.

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[1] *See* Centers for Disease Control, National Diabetes Statistics Report, 2017, p. 10.

[2] *Id.*

11. Further, the blood glucose levels of some diabetics are prone to wild and rapid swings either up or down. For example, in the span of minutes, glucose levels may drop precipitously low and the patient may fall into a diabetic coma that proves fatal. This is referred to as "brittle diabetes" and Mrs. Zieroth suffers from this condition.

12. It is estimated that one in 20 individuals with brittle diabetes dies each year in their sleep due to an undetected fatal low blood sugar. This is known as "dead in bed syndrome."[3]

13. For such individuals, effectively monitoring and managing glucose levels requires that continuous real-time glucose data needs to be available throughout each 24 hour period so that proper insulin delivery can be determined and delivered, whether by injection or by continuous subcutaneous insulin infusion through an insulin pump.

A. Diabetes Treatment

14. Medicare established the goal for diabetes treatment of Medicare beneficiaries when they issued the Decision Memo in 1999 approving Medicare coverage of continuous subcutaneous insulin infusion pumps: "The goal for diabetes treatment should be to obtain as close to normal blood glucose levels as possible. … The fact that [a Type I diabetic] turn 65 years of age does not change the nature of their disease, nor their potential success using the pump. … it seems reasonable to extrapolate the data from the available studies to suggest a benefit of tight control in Medicare beneficiaries as well." CMS Decision Memo for Insulin Infusion Pump - CAG-00041N-August 26, 1999 at 12-13. The same logic applies to continuous glucose monitors.

[3] https://www.diapedia.org/acute-and-chronic-complications-of-diabetes/7105157816/dead-in-bed-syndrome (accessed October 9, 2018).

B. Glucose Tests

15. Prior to the early 2000's, the most common method for patients to monitor blood glucose levels was by pricking a finger to draw blood (a significant advance at the time to the urine test strips), and this method is still used today. The drawn blood is placed on a test strip coated with glucose oxidase. Glucose in the blood and the glucose oxidase on the test strip react and, in doing so, consume oxygen. The oxygen consumption results in a reaction that can be detected, either as an electrical charge that is measured by a glucose meter, or as change in color on the test strip which is correlated with actual blood glucose levels.

16. This method has several disadvantages. First, it requires patients to prick their fingers multiple (*e.g.*, 12) times a day. Further, because some of those times will be when the patient is sleeping, the patient must awake throughout the night and cannot get a full night's sleep. This lack of restful sleep has significant adverse medical consequences similar to sleep apnea, including short term metabolic impacts that can impact blood sugar and long term medical complications. Second, because testing is done on relatively long intervals of several hours, brittle diabetes patients may suffer an episode between testing periods. Thus, a brittle diabetes patient fully compliant with this testing procedure may still suffer adverse hypo/hyper glycemic consequences or die because the onset of symptoms is so quick, occurring between testing intervals.

C. Continuous Glucose Monitors

17. The disadvantages of finger prick/test strips led researchers to develop continuous glucose monitors which became available starting in the mid-2000s. When using a CGM, a disposable sensor is placed below the skin in the space between tissues (interstitial space) that is filled with fluids going to and from cells. These interstitial fluids contain glucose that has come

from the blood and is on the way to the cells. Thus, interstitial glucose is correlated with the glucose in blood itself. Current CGM sensors last for approximately a week and measure glucose levels every five to seven minutes (*i.e.*, nearly 300 times/day) without requiring patient interaction - including when the patient is sleeping.

18. The output from a CGM sensor is sent automatically, via a transmitter, to an insulin pump that incorporates the CGM receiver/monitor and/or a smart phone/tablet. A CGM transmitter typically lasts for several months to several years. The CGM receiver/monitor or smart phone/tablet monitors the detected glucose levels and reports the results to the patient, healthcare provider, or device supplier internet portal, and can trigger an alert or, in the case of newer CGM, can suspend or adjust the delivery of insulin. Further, the CGM receiver/monitor or an application on a smart phone or tablet can plot glucose trends and perform further analyses.

19. Typically, the CGM is calibrated by finger prick/test strip testing at least twice a day.

20. Accordingly, CGMs offer many advantages over finger prick/test strips. First, they monitor glucose levels much more frequently and for an entire 24-hour day - meaning that brittle diabetes patients have complete data necessary to properly manage blood glucose and enjoy decreased risk of death from a rapid onset of hypo/hyperglycemic symptoms. Second, even for non-brittle diabetes patients, the increased monitoring frequency detects changes in glucose levels more quickly, usually before the patient feels physical symptoms, and leads to much finer glucose level control, thereby reducing diabetes related health complications. Third, once the CGM is inserted the monitoring occurs without patient interaction other than calibrations - meaning that patients can sleep through the night and/or not interrupt their regular activities. Fourth, patients

are not required to prick themselves as frequently – meaning that they do not suffer from near continuous injuries and sources of infection and discomfort.

21. The CGM provides trend information regarding how quickly glucose levels are dropping or rising. The trend information is used by patients and clinicians for the immediate short term management of their diabetes (*e.g.*, "Do I have time to make it to the lunch meeting or should I pull over now and drink juice?"), and for the long term management of diabetes (*e.g.*, the patient is experiencing more frequent lows and extreme fluctuations in warm weather and thus should take higher and more frequent doses of glucose in summer months).

22. Overall, these advantages lead to improved glucose management and therapy, increased quality of life, and reduced risk of death or other complications.

23. Moreover, CGMs result in decreased health care costs and improved outcomes. Because complications related to glucose control are reduced/avoided, the overall expense of treating a diabetic patient is reduced. For example, many diabetic patients require ambulance transport to the hospital when they suffer an incident. In 2014, more than 450,000 emergency room visits were the result of hyperglycemic or hypoglycemic incidents among diabetics.[4] These episodes are very expensive and a CGM reduces their frequency. Of course, the ultimate cost is death and CGMs reduce the events that can lead to that result.

D. CGM Cost Coverage

24. Sensors for modern CGMs cost approximately $300 - $550/month over the course of a year for purchase of the one-week sensors.

25. The advantages of CGMs over finger pricks/test strips are widely recognized in the health care field. Indeed, CGMs have become the medically recommended standard of care for

[4] *See* Centers for Disease Control, National Diabetes Statistics Report, 2017, p. 9.

treating Type I, particularly brittle, diabetes. As a result, ~98% of private health care providers cover CGM-related costs,[5] indicating their conclusion that covering the cost of the CGM is the cost-efficient approach, compared to covering the costs of ambulances, emergency room visits, hospital admissions, more serious complications and the other increased health care costs of patients without CGMs.

26. For many patients, doctors describe a CGM as "life-saving."

27. Inexplicably, Medicare has continued to resist covering CGMs. Except with regard to one CGM system payment for which is calculated based on equivalent cost of limited blood glucose test strips rather than the higher cost sensors, [6] Medicare deems CGMs "not primarily and customarily used to serve a medical purpose" – contrary to logic and medical opinion – and, therefore, not covered durable medical equipment (DME).

E. Durable Medical Equipment Medicare Benefit Category

28. Medicare covers "durable medical equipment." Pursuant to 42 U.S.C. § 1395x(n), "durable medical equipment" is not defined, except by example that CMS has recognized is not a complete list. One such example is "blood glucose monitors."

29. The Secretary has issued regulations further setting forth a five-part test to determine whether equipment is "durable medical equipment" within the meaning of § 1395x(n) (see 42 C.F.R. § 404.202). Equipment is considered "durable medical equipment" if it:

a) Can withstand repeated use;
b) Has an expected life of at least 3 years;
c) Is primarily and customarily used to serve a medical purpose;
d) Generally is not useful to an individual in the absence of illness or injury; and
e) Is appropriate for use in the home.

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[5] *See* https://provider.dexcom.com/reimbursement/commercial-reimbursement

[6] *See* Food and Drug Administration, Premarket Approval P120005/S041 (December 20, 2016).

F. CMS-1682-R

30. Pursuant to 42 U.S.C. § 1395hh(2):

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

31. The "paragraph (1)" referred to requires "notice and comment" as described in the remainder of 42 U.S.C. § 1395hh.

32. Without notice and comment, on January 12, 2017, CMS issued Ruling No. CMS-1682-R as CMS' "final opinion and order" with regard to CGM coverage.

33. By its own terms, that Ruling is "binding on all CMS components, on all Department of Health and Human Services components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration …".

34. The Ruling addresses whether CGMs are DME and, therefore, covered within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

35. As set forth in the Ruling, if a CGM does not completely replace finger prick/test strips, CMS considers the device not "primarily and customarily used to serve a medical purpose." This is so, CMS contends – contrary to the facts – because patients do not "mak[e] diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM[.]" See CMS-1682-R at 6-7. CMS calls these CGM's "non-therapeutic."

36. The Ruling also notes that one CGM that has been FDA approved to completely replace finger pricks/test strips is DME (the Dexcom G5). See CMS-1682-R at 7-10. In particular, the Ruling determines that the receiver/monitor portion of a CGM lasts more than 3 years and, including other factors, that the whole system is DME within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

37. Both before and after issuance of CMS-1682-R, the Secretary has refused coverage of CGM devices made by Medtronic and Dexcom (other than the Dexcom G5) on the grounds that they are not "primarily and customarily used to serve a medical purpose."

38. Further, as a result of CMS-1682-R, the discretion ALJs previously had to award coverage (even in the face of an alleged LCD) was eliminated. As a result, it is futile to submit claims for non-Dexcom G5 devices with dates of service after January 12, 2017. Because the ALJs no longer have discretion, those claims must be denied.

39. Without notice and comment, CMS-1682-R was incorporated into LCD L33822 and Policy Article A52464, generally excluding CGMs.

40. Thus, the Ruling substituted the non-statutory/regulatory term "therapeutic" for the previous non-statutory/regulatory term "precautionary" as the criteria/basis for denials.

G. Other Litigation Related to CGMs

41. In general, the Secretary has refused to cover CGMs on the grounds that a CGM is not durable medical equipment. National Coverage Determination (NCD) 280.1. This is so, the Secretary contends, because CGMs are not "primarily and customarily used to serve a medical purpose."

42. Instead, the Secretary contends that a CGM is excluded from coverage as "precautionary" – a non-statutory term. Although there was no national coverage determination (NCD) excluding CGM coverage, a local coverage determination (LCD) and policy article (PA) described CGMs as excluded as "precautionary." LCD L33822 and Policy Article P A52464.

43. The Secretary's refusal to cover CGMs has been the subject of numerous litigations.

44. As to the Secretary's base position that a CGM is not "primarily and customarily used to serve a medical purpose", that position has been rejected by three district courts.

45. In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.) and *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.), the district courts found that the Secretary's claim that a CGM is not "primarily and customarily used to serve a medical purpose" was erroneous, not supported by substantial evidence, and in each case, the Medicare beneficiary was entitled to durable medical equipment coverage and ordered the Secretary to provide CGM coverage.

46. Further, in the *Whitcomb* case, the court found that the Secretary's position was "arbitrary and capricious" and "unreasonable." Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.) at 14, 12.

47. In addition, all three courts found that the Secretary's position lacked "substantial justification" and awarded reimbursement and attorney's fees to the plaintiffs pursuant to the Equal Access to Justice Act. *See* 5 U.S.C. § 504.

48. Likewise, the Secretary's own Civil Remedies Division concluded that exclusion of CGM coverage on the grounds that a CGM is "precautionary" did not pass the "reasonableness standard." *See* DAB No. CR4596, 2016 WL 2851236 at *18.

H. Prosthetic Device Medicare Benefit Category

49. The benefits provided by Medicare include entitlement to have payment made for "medical and other health services". (Section 1832(a)(1) (42 U.S.C. 1395k(a)(1) of the Social Security Act) "Medical and other health services" are defined in Section 1861(s) of the Act to mean:

> "any of the following items or services:
> ...
> (6) durable medical equipment;
> ...

> (8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care) including replacement of such devices …" (Section 1861(s) (42 U.S.C. 1395x(s) of the Social Security Act)) [emphasis added]

The plain meaning of the term "any" confirms entitlement of Medicare coverage of one or more of the medical and other health services listed. Sharon Zieroth is entitled to Medicare coverage of her Medtronic MiniMed 530G System, inclusive of Enlite® Sensors as durable medical equipment and, separately and independently, as a prosthetic device that replaces part of the internal body organ, the pancreas.

50. The Medicare Benefit Policy Manual describes Medicare coverage for prosthetic devices:

"Prosthetic devices which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician's order." (Medicare Benefits Policy Manual, Chapter 15, Section 120.A at 127) [emphasis added]

51. The Medicare Benefits Policy Manual provides a textbook description of Sharon Zieroth's entitlement to Medicare coverage of the Medtronic MiniMed 530G System, inclusive of the Enlite® Sensor, that was approved by the FDA as an Artificial Pancreas Device System – Threshold Suspend, and as user programmable and controllable to deliver insulin at user set low glucose threshold, and that replaces part of an internal body organ [pancreas] and part of the function of a permanently inoperative or malfunctioning internal body organ [endocrine function of suspending insulin delivery of permanently inoperative/malfunctioning pancreas of Type I diabetic]. The Medtronic MiniMed 530G System, inclusive of the Enlite® Sensor, replaces part of the pancreas to provide endocrine functionality for continuous metabolic monitoring with

respect to blood glucose and automatic suspension of insulin delivery to protect against dangerous hypoglycemic conditions.

V. Facts Specific to Mrs. Zieroth

52. Sharon Zieroth is a 72-year old mother of two with two small grandchildren

53. First diagnosed with Type I diabetes at the age of twenty (20), Mrs. Zieroth is a "brittle" diabetic (*i.e.*, her glucose levels are prone to wild and rapid swings). In addition, Mrs. Zieroth suffers from hypo/hyperglycemic unawareness (*i.e.*, she has no physical sensations – head aches, sweats, etc. – that alert her glucose levels need to be adjusted). Prior to receiving an insulin pump and a CGM, Mrs. Zieroth had numerous paramedic and emergency room interventions because of her uncontrolled diabetic condition.

54. In January 2015, Mrs. Zieroth was prescribed a Medtronic MiniMed 5303G System by her treating physician. Given Mrs. Zieroth's brittle diabetes, hypo/hyperglycemic unawareness, and prior medical history, traditional finger stick checking was obviously not sufficient to manage Mrs. Zieroth's diabetes. The CGM eliminated/reduced Mrs. Zieroth's risk of death and other medical complications.

55. The Medtronic MiniMed CGM communicates with Mrs.Zieroth's insulin pump to alert Mrs. Zieroth of out of range glucose levels and to automatically suspend insulin delivery, without user intervention or a user blood glucose meter test, thereby protecting against potentially life-threatening hypoglycemia. Since receiving an insulin pump and the CGM which interfaces with it, Mrs. Zieroth has not had to visit the Emergency Room as a result of her diabetic condition.

VI. The Claim at Issue in this Case

56. On July 6 and December 14, 2017, and May 16, 2018, Mrs. Zieroth received supplies related to her CGM, including sensors.

57. The total cost of these sensors was $4,257.00.

58. Mrs. Zieroth's claims for coverage for these sensors were rejected on July 21, 2017, January 5, 2018, and June 22, 2018, respectively, on the stated grounds that "Medicare does not pay for this item or service." Thereafter, Mrs. Zieroth sought redetermination.

59. Mrs. Zieroth's requests for redetermination were denied on May 22, 2018, May 30, 2018, and December 5, 2018, respectively, on the stated grounds that Mrs.Zieroth's CGM did not meet the definition of "therapeutic" in CMS 1682-R and, therefore, that coverage was barred. Thereafter, Mrs. Zieroth sought reconsideration.

60. Mrs. Zieroth's requests for reconsideration were denied on January 12, 2019 and February 25, 2019. Mrs.Zieroth's requests were denied on the grounds that, pursuant to CMS1682-R and LCD L33822, Mrs. Zieroth's CGM was "precautionary," not "primarily and customarily used to serve a medical purpose", and, therefore, not "durable medical equipment." Thereafter, Mrs. Zieroth filed appeals that were assigned to ALJIan Midgley.

61. After conducting a hearing on June 3, 2019, in which CMS chose not to participate, on August 5, 2019, ALJ Midgley issued decisions (ALJ Appeal No.s 1-8354608581, 1-8354608710, and 1-8354608963, respectively). There, ALJ Midgley found that:

> The disposable sensor and external transmitter supplies provided to the Appellant on [respective Date of Service] are covered by Medicare. Id. at5.

A particularly important portion of ALJ Midgley's analysis follows:

62. CMS-1682-R permits therapeutic devices other than the Dexcom G5, and because the Medtronic makes medical decisions and adjusts insulin without human input or additional testing, I do not find it simply a convenience item. The CGM enables Appellant to effectively manage her diabetes and avoid the severe and adverse consequences of her recurrent daily episodes of hypoglycemia. The record demonstrates medical neccessity for the CGM disposable sensor and external transmitter and substantial compliance with Medicare's coverage criteria.".

63. Thereafter, CMS through its AdQIC contractor, Q2 Administrators, referred ALJMidgley's's decision to the Medicare Appeals Council for own motion review on the basis that the decisions contain errors of law material to the outcome of the claims. In particular, CMS alleged ALJ Midgley erred as a matter of law by misapplying CMS 1682-R (the Ruling) with respect to Appellant's CGM and the sensors at issue.

64. On December 18, 2019, the Council issued a decision (M-19-3084) reversing ALJ Midgley's decision and denying coverage. In particular, the Council rejected Mrs. Zieroth's claim on the grounds that the FDA has not approved the Medtronic CGM as a replacement for a blood glucose meter, that the sensor code is denied as statutorily non-covered, no benefit, because they are not necessary supply for the effective use of the infusion pump component and that appellant had not submitted evidence to support the prosthetic device argument or to show that appellant's pancreas was inoperative or malfunctioning or that the Medtronic CGM system replaces all or part of the pancreas or its functions. Accordingly, the Council rejected Mrs.Zieroth's claim on the grounds that the Medtronic CGM is not "durable medical equipment" or "prosthetic device".

65. This suit was filed within 60 days after receipt of the Council's decision on December 23, 2019.

VII. CAUSES OF ACTION

COUNT I
Violation of 5 U.S.C. § 706(1)
(unlawfully withheld or unreasonably delayed)

66. Paragraphs 1-65 are incorporated by reference as if fully set forth herein.

67. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical

equipment and/or a prosthetic device and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

68. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as unlawfully withheld or unreasonably delayed and unsupported by the evidence, and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make appropriate payment at the statutory rate of 80% of the covered cost for the claims that are the subject of this case.

COUNT II
Violation of 5 U.S.C § 706(2)(A)
(arbitrary and capricious, abuse of discretion, not in accordance with law)

69. Paragraphs 1-68 are incorporated by reference as if fully set forth herein.

70. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

71. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT III
Violation of 5 U.S.C § 706(2)(C)
(in excess of statutory jurisdiction, authority, or limitations or short of statutory right)

72. Paragraphs 1-71 are incorporated by reference as if fully set forth herein.

73. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

74. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision as in excess of the Secretary's authority and limitations and short of Plaintiff's statutory rights and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT IV
Violation of 5 U.S.C § 706(2)(D)
(without observance of procedure required by law)

75. Paragraphs 1-74 are incorporated by reference as if fully set forth herein.

76. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

77. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision as done without observance of the procedure required by law (*e.g.*, notice and comment required for modification of policy) and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT V
Violation of 5 U.S.C § 706(2)(E)
(not supported by substantial evidence)

78. Paragraphs 1-77 are incorporated by reference as if fully set forth herein.

79. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

80. CGM is recognized nationally and internationally by clinicians, researchers, and payers as a reasonable and medically necessary medical device which is the standard of care for individuals suffering from brittle diabetes.

81. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision as not supported by substantial evidence and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT VI
Violation of 42 U.S.C § 1395hh
(without observance of regulation promulgation)

82. Paragraphs 1-81 are incorporated by reference as if fully set forth herein.

83. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

84. Based on the foregoing, Plaintiff asks the Court to declare that CMS-1682-R issued in violation of 42 U.S.C. § 1395hh, as it is a statement of policy published without a

notice/comment period establishing/changing a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals to receive services or benefits, reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and/or a prosthetic device and direct the Secretary to make payment for the claims that are the subject of this case.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court:

A. Enter an order:

(1) setting aside CMS-1682-R and its determination that CGMs that do not completely replace finger prick/test strips are not DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(2) setting aside CMS-1682-R as issued in violation of law;

(3) finding that CGMs (whether they completely replace finger prick/test strips or not) are DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(4) finding the CGM are prosthetic devices within the meaning of 42 U.S.C. §1395x(s)(8)

(5) directing Defendant to provide coverage for Mrs.Zieroth's claims and

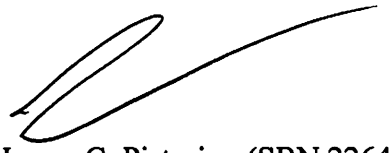
(6) finding the Secretary's denials of CGM coverage on the grounds that a CGM is not DME or a prosthetic device are not supported by substantial evidence, are arbitrary and capricious, an abuse of discretion, and not in accordance with the law.

B. Award attorney's fees and costs to Plaintiffs as permitted by law; and

C. Such further and other relief this Court deems appropriate.

Dated: January 7, 2019

Respectfully submitted,



James C. Pistorino (SBN 226496)
james@dparrishlaw.com
Parrish Law Offices
224 Lexington Dr.
Menlo Park, CA 94025
Telephone: (650) 400-0043
Attorneys for Plaintiff